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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,924

07/15/2003

Gopi Venkatesh

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7145

27805

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05/05/2008

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/619,924	Applicant(s) VENKATESH ET AL.	
	Examiner S. Tran	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/04/08 has been entered.

Claim Rejections - 35 USC § 103

Claims 1-5, 7-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gantt et al. WO 01/43725 A1, in view of Bins US 4,777,044.

Gantt teaches a process for preparing a controlled release potassium chloride (KCl) tablet comprising coating KCl particles with two coating layers by coacervation using polyethylene as a phase separator, blending the coated KCl particles with excipients, and then compressing the blended mixture into tablet (abstract; pages 3-4). First coating layer comprises ethyl cellulose having viscosity of about 90 to about 110 cp (page 3, 1st and 2nd paragraphs). Second coating layer comprises polyvinyl pyrrolidone, ethyl cellulose, hydroxypropylmethyl cellulose, or combination thereof (page 3, 3rd paragraph). Plasticizer such as triacetin, triethyl citrate, dibutyl sebacate, or PEG 400 is included in the second coating composition (page 3, 4th paragraph). Excipient includes binder, disintegrant (microcrystalline cellulose), wetting agent

(surfactant), and lubricating agent (page 4, last paragraph through page 5, 1st paragraph).

Gantt does not explicitly teach the claimed silicon dioxide.

Bins teaches a dry compressed ammonium nitrate tablet comprising solid ammonium nitrate and tableting auxiliary (abstract). Suitable tableting auxiliary includes microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate (column 1, lines 60 through column 2, lines 1-7). Bins also teaches the claimed tablet hardness in the use of colloidal silicon dioxide, namely, tablet hardness of at least 15 kP (column 2, lines 20-22). Bins also teaches the amount of microcrystalline cellulose is from 5%-50%, and the amount of colloidal silicon dioxide is from 0.05%-10% (column 2, lines 3-7).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tablet composition of Gantt to include silicon dioxide as the tableting auxiliary in view of the teachings of Bins, because Bins teaches using colloidal silicon dioxide in a compressed tablet formulation is well known in the art, because Bins teaches using colloidal silicon dioxide to obtain tablet hardness at a level that gives the best results when coated, because Bins teaches suitable and acceptable tablet hardness is obtained in the use of colloidal silicon dioxide, and because Gantt teaches the use of pharmaceutically acceptable excipient suitable for compressed tablet.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gantt et al. WO 01/43725 A1, in view of Vilkov et al. US 5,807,579.

Gantt is relied upon for the reason stated above. Gantt does not teach using colloidal silicon dioxide, and the claimed plasticizing agent.

Vilkov teaches a pharmaceutical tablet composition for oral administration comprising an active agent, and suitable tablet excipients including talc, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate. The tablet has a hardness of 9-17 kP (column 5, lines 60-67). Vilkov also teaches coating comprising plasticizing agent such as triethyl citrate and diethyl phthalate (column 4, lines 33-42). Vilkov further teaches the amount of colloidal silicon dioxide (column 6, lines 3-13). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tablet formulation of Gantt to include colloidal silicon dioxide as a tablet excipient, and diethyl phthalate as a plasticizing agent to obtain the claimed invention. This is because Vilkov teaches the equivalency of diethyl phthalate with other well known plasticizing agent, because Vilkov teaches using colloidal silicon dioxide is a well known tablet excipient, because Gantt teaches the use of tablet excipients, and because Gantt teaches the use of other plasticizing agents in the compressed tablet formulation.

Response to Arguments

Applicant's arguments filed 01/04/08 have been fully considered but they are not persuasive.

Applicant argues that neither Sheth nor Remington teaches the claimed tablet hardness.

In response to applicant's argument, the rejections in view of Sheth or Remington have been withdrawn in view of new rejections over Vilkov and Bins.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618

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